

helpful suggestion, and claims 16 and 17 have been added. Claims 13 and 15 have been rewritten as new independent claim 16 pursuant to the Examiner's helpful suggestion. New dependent claim 17 is from original claim 14. Claims 1-17 are in the case and are before the Examiner.

1. The Amendments

Although it cannot be agreed that the previous title was not descriptive, the title has been amended as requested to make it more descriptive of the claimed invention.

Claim 10 has been amended to recite the language of the independent claim from which it depends. Claims 16 and 17 have been added as requested in the Action. These claims are rewritten versions of claims 13 and 15, with new claim 17 being a rewritten version of claim 14.

It is thus seen that no new matter has been added.

2. Rejection for Nonstatutory Double Patenting

A. Double Patenting

The claims have been provisionally rejected under the judicially created doctrine of double patenting over the claims 1-14 of co-pending application Serial No. 09/146,261 that was

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filed on the same date as the present application, September 3, 1998. The rejection was said to be provisional because the "conflicting claims have not yet been patented."

The Action asserted that the subject matter claimed herein is "fully disclosed in the referenced copending application". The Action continued by asserting that "there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application."

Inasmuch as none of the claims of co-pending application Serial No. 09/146,261 has been allowed, let alone issued in a patent, this rejection is premature. This rejection will be reviewed again once either of the applications has matured into a patent.

It is further noted for the record that it is respectfully believed that the present claims could not be presented in the referenced application as the scope of these claims differs from that of the other application.

B. Common Ownership

The Action noted that copending application Serial No. 09/146,261 could be deemed prior art under 35 U.S.C. §103(a).

In response, it will be noted that the three named inventors of the other application are also inventors here. Upon information from Dr. Clemente, the Chairman of the Board of the assignee, the undersigned is informed that those three individuals and the other two named here were all employed by the assignee at the time the inventions were made and all had a duty to assign their inventions to the assignee. Should the Examiner require a further showing, it is requested that the specifics required be delineated in the next Action or by telephone.

3. Rejection Under 33 U.S.C. §112, Second Paragraph

Claim 10 was noted as lacking an antecedent basis for the word "beads". The Examiner is thanked for noting that point, and claim 10 has been appropriately amended.

Claims 13-15 were rejected as allegedly being indefinite, and it was requested that the claims "recite a method of treating a febrile child". The latter of these two requests has been carried out in the present amendments. However, it is not seen how the original claims were in any way indefinite, and those claims have been consequently maintained.

This basis for the rejection is therefore respectfully traversed.

It is submitted that the present Action provided only a conclusionary statement as to the alleged indefiniteness of claims 13-15. Neither a supporting argument nor a case citation was provided in support of this position. It is respectfully requested that the reasoning behind this conclusion be provided if this rejection is repeated so that that reasoning can be considered and rebutted, if necessary.

It is submitted that the preamble of claim 13 recites that the treatment is for "a human patient that has difficulty swallowing acetaminophen in tablet, caplet or capsule form..." As such, the claim recites a way to overcome difficulty swallowing the recited dosage forms by use of the particles of claim 1 in a palatable medium. It is therefore believed that the recited language is definite, and that this rejection should be withdrawn.

4. Rejection Under 35 U.S.C. §103(a)

The claims were rejected as allegedly obvious from the collective disclosures of Patel U.S. Patent No. 4,867,984 (hereinafter Patel), Shah et al. U.S. Patent No. 5,773,031

(hereinafter Shah) and Habib et al. U.S. Patent No. 5,780,055 (hereinafter Habib). This basis for rejection is respectfully traversed as is discussed below.

It is first submitted that the Habib disclosure is inapposite to the present invention and should be withdrawn as a reference against these claims. Thus, as is pointed out in the "SUMMARY OF THE INVENTION" at column 24, lines 26-63, the Habib disclosure is directed to compactible so-called "cushioning beads" that are used in the preparation of tablets and the tablets made using those beads. The cushioning beads are themselves made of microcrystalline cellulose and are "prepared by extrusion-spheronization, followed by freeze-drying." (Column 24, lines 54-55.) If only because the relied-on disclosure is directed to a totally different invention, this basis for rejection is respectfully traversed.

It is respectfully submitted that the Action has taken the several disclosures of Habib, found snippets that broadly relate to the present invention, disregarded disclosures that are contrary to the claimed invention, and then joined those disparate disclosures to try to arrive at the claimed invention. This approach is inappropriate and has been rejected by the

Court. Thus, in *In re Wesslau*, 147 USPQ 391,393 (CCPA 1965) the Court pointed out that

[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.

Here, the Action has overlooked the fact that the claimed subject matter is directed to acetaminophen-containing particles (claim 1) and to a processes that use those particles distributed in a palatable medium (claims 13 and 16), whereas Habib teaches specifically produced, active ingredient-free cushioning beads that are compacted into tablets with the active ingredients. As is specifically noted in claim 13, this invention is in part directed a dosage form that avoids some of the problems associated with tablets. Thus, the Habib teaching that is solely directed toward tablet preparation is inapposite to the present invention, and should be withdrawn as a reference against the claims, as should the present rejection.

The Shah and Patel disclosures are more to the point. However, the present invention is directed to a particulate composition that exhibits a specific, recited *in vitro* release rate under specified conditions. A composition with a recited

release rate is no where taught nor suggested in Habib, nor in Shah or Patel, nor of course, is the specific release rate recited here.

Such a composition could not be either taught or disclosed in Habib because that teaching is directed to tablets, not particles. Similarly, as was noted in the last sentence of the Action that discussed the Shah patent, those disclosures are directed to "compressed tablets, capsules or pouches", and each example in that patent was so directed.

The Patel teaching suffers from the same problem. It too teaches a sustained release acetaminophen composition, but neglects to teach the skilled worker any release profile that the composition should have. It is therefore requested that this rejection be withdrawn.

The Action also asserts that a blend of both immediate and sustained release particles is well known to provide "both an instant relief to a patient as well as a prolonged effect over a period of 4-8 hours." It is submitted, however, that the relied-upon art is not seen to provide that disclosure in conjunction with the compositions relied-upon in the Action. It is requested pursuant to 37 C.F.R. § 1.104(d)(2) that the location(s) of that "well known" fact be provided in the context

of the recited art so that it can be addressed in its context, should this rejection be repeated.

The Action also appears to totally disregard the surprising results obtained using a composition of the claims. Those results are discussed in the text beginning at line 21 of page 39. There is neither teaching nor suggestion in the relied-on teachings that such results would or could be obtained with any composition, let alone a composition of the claims. It is again therefore submitted that this rejection should be withdrawn.

5. Further Art

Pursuant to 37 C.F.R. §1.97, a list of documents that may be material to the examination of this application is provided on the attached Form PTO-1449. Copies of Documents are bound and enclosed herewith. The disclosures of these documents are discussed in the application. Also enclosed are copies of the International Search Reports for the corresponding PCT application here and the PCT application corresponding to U.S. Patent Application Serial No. 09/146,261.

Documents for which the supplied date of publication lists the year of publication without the month were published



sufficiently earlier than the effective U.S. filing date and any foreign priority date, so that the particular month of publication is not in issue. Pursuant to §609 of the MPEP, it is understood that the month of publication is not required when the particular month of publication is not in issue.

No inferences should be drawn that the attached list represents a comprehensive investigation, or that any material disclosed is equivalent to the subject invention. In addition, none of the documents that have publication dates prior to the priority date of the above application anticipate the invention in this application.

The cited documents disclose numerous specific features. There has been no attempt to list each and every feature disclosed by each document. The Examiner is requested to review the documents and determine the extent of the materiality of the document disclosures with respect to the present invention.

The discussion of any art and the citation of any document herein is not to be construed as an admission that the art or document disclosure is necessarily within the invention field of endeavor, that the art or document disclosure is necessarily prior in time to a particular date which may be

relevant to the instant patent application, and/or that the art or document disclosure is otherwise necessarily prior art as defined by the patent law with respect to the instant invention and application.

Also, there is reserved the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosures of the art and documents recited herein, that may be cited by the Examiner in rejecting a claim in the instant patent application.

The recitation herein of the art and documents is not to be construed as an assertion that more pertinent art could not possibly be in existence.

#### 6. Summary


The title has been amended and claim 10 has been amended as noted in the Action. Claim 13 has been rewritten with claim 15 as independent claim 16, and claim 14 has been rewritten as new claim 17 that is dependent upon claim 16. Each of the bases for rejection has been dealt with and overcome or made moot. It is therefore believed that this application is in condition for allowance. An early notice to that effect is earnestly solicited.

It appears that the original number of independent claims was inadvertently noted as one when two independent claims were originally present. New independent claim 17 makes the new total of independent claims three, the number permitted without an added claim fee.

The fee of 37 C.F.R §1.97 is enclosed herewith. No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,

By   
Edward P. Gamson, Reg. No. 29,381

Enclosures

Petition for Two-Month Extension of Time and Fee  
IDS, and fee  
One Bound Volume of Art (A1-A6)

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